

Caire Inc. a Chart Industries Company

Suite 316

1800 Sandy Plains Industrial Parkway

Marietta, GA 30066-6363

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www.chart-ind.com

DECLARATION OF CONFORMITY

Business Unit Name/Address: Caire, Inc.

Chart BioMedical Division

1800 Sandy Plains Industrial Pkwy, Suite 316

Marietta, GA 30066 USA

Manufacturing Facilities Address: Caire, Inc.

Chart BioMedical Ltd.

2000 Airport Industrial Drive

Unit 2 - Maxdata Centre

Ball Ground, GA 30107 USA

Downmill Rd Bracknell. Berkshire

RG12 1QC

United Kingdom

TPED/MDD Representative: MPS

Medical Product Service GmbH

Borngasse 20

35619 Braunfels, Germany

Product Families: Portable Liquid Oxygen Units

Base Liquid Oxygen Units

MDD Equipment Class: Class IIa, MDD appendix II

This declaration applies to all CE marked devices manufactured from the date of issuance until it is either superseded by another declaration or withdrawn. I, the undersigned, hereby declare the equipment specified above, is in accordance with the following <u>Directives</u>:

1.) Module D1 of the European Council Directive 99/36 EC for Transportable Pressure Equipment Directive (Certificate Number: 05/US/919))

2.) Appendix II of the Medical Devices Directive 93/42/EC

(Certificate Number: 05/US/920)

and the following Standard:

1.) EN - ISO 13485 (2003)

Ref 10823887 Rev W

(Certificate Number: 05/US/920)

Notified Body: APRAGAZ (0029)

Vilvoordesesteenweg, 156 Chaussée de Vilvorde, 156 1120 Brussels, Belgium

Start of Pi Marking: 13 December 2002 Start of CE Marking: 12 February 1998

Model(s): N/A Serial Number(s): N/A

To the best of my knowledge, the information above is accurate and was in effect from Feb 06, 2007, thru to Mar 6, 2008. This applies to all listed products above manufactured within the effective dates.

| | 1805 Wakepailes | | | |
|---------------|-------------------------------|-------|--------------|--|
| Signature: | | Date: | Mar 20, 2024 | |
| Position: | Quality Supervisor/Regulatory | | | |
| Name (Print): | Ted Vlahopoulos | | | |